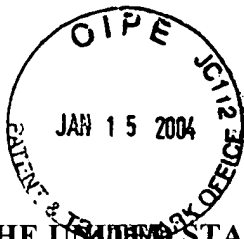


S/N 09/689136



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	John F. Engelhardt et al.	Examiner:	Daniel M Sullivan
Serial No.:	09/689136	Group Art Unit:	1636
Filed:	October 12, 2000	Docket:	875.032US1
Title:	COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION		

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(c)(2), Applicants have included the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 19-0743.

01/16/2004 SSANDARA 00000012 09689136

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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

JOHN F. ENGELHARDT ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6959

Date

January 12, 2004

By

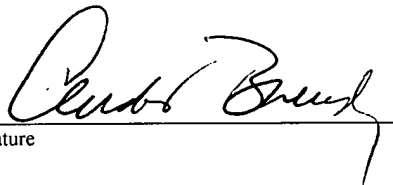
Janet E. Embretson  
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of January, 2004.

Candis B. Buending

Name

Signature

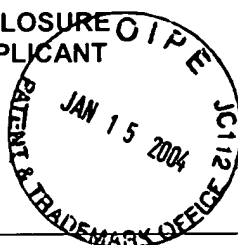


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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

Application Number	09/689136
Filing Date	October 12, 2000
First Named Inventor	Engelhardt, John
Group Art Unit	1636
Examiner Name	Sullivan, Daniel

Sheet 1 of 2

Attorney Docket No: 875.032US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-2002/0197237	12/26/2002	Engelhardt, J. , et al.	424	93.2	01/22/2002
	US-20020076754	06/20/2002	Sun, Liangwu , et al.	435	69.1	04/20/2001
	US-20020131956 A1	09/19/2002	Walsh, C. E., et al.	424	93.2	03/12/2002
	US-5,843,742	12/01/1998	Natsoulis, G. , et al.	435	172.3	09/08/1995
	US-6,156,303	12/05/2000	Russell, D. W., et al.	424	93.2	06/11/1997
	US-6,221,349	04/24/2001	Couto, Linda B., et al.	424	93.2	07/30/1999
	US-6,287,569	09/11/2001	Kipps, T. J., et al.	424	199.1	04/06/1998
	US-6,436,392	08/20/2002	Engelhardt, John F., et al.	424	93.2	03/25/1999
	US-6,544,786	04/08/2003	Xiao, Xiao , et al.	435	325	10/13/2000

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T <sup>2</sup>
	WO-01/83692	11/08/2001	Hildinger, M. , et al.	C12 N		

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BERNS, K. I., et al., "Biology of Adeno-associated Virus", In: <u>Current Topics in Microbiology and Immunology</u> , 218, Springer-Verlag, Berlin: R.W. Compans, et al., (Eds.), (1996), pp. 1-23	
		BERNS, K. I., "Parvovirus Replication", <u>Microbiological Reviews</u> , 54 (3), (Sept. 1990), pp. 316-329	
		DUAN, Dongsheng , et al., "Circular intermediates of recombinant adeno-associated virus having defined structural characteristics responsible for long-term episomal persistence in muscle tissue", <u>J. of Virology</u> , 72 (11), (Nov. 1998), pp. 8568-8577	
		DUAN, Dongsheng , et al., "Endosomal processing limits gene transfer to polarized airway epithelia by adeno-associated virus", <u>Journal of Clinical Investigation</u> , vol. 105, number 11, (June 2000), 1573-1587	
		DUAN, Dongsheng , et al., "Structural Analysis of adeno-associated virus transduction circular intermediates", <u>Virology</u> , 261 (1), (Aug. 1999), pp. 8-14	
		DUAN, Dongsheng , et al., "Structural and functional heterogeneity of integrated recombinant AAV genomes", <u>Virus Research</u> , 48 (1), (Jan. 1997), pp. 41-56	
		ENGELHARDT, John , et al., "Adeno-Associated Virus Vectors", <u>U.S. Provisional Application SN 60/086,166, FILED May 20, 1998 (875.005PRV)</u> .	
		ENGELHARDT, John , et al., "Compounds And Methods To Enhance Adeno-Associated Virus Transduction", <u>U.S. Provisional Application SN 60/138,188, filed June 8, 1999 (875.012PRV)</u> .	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

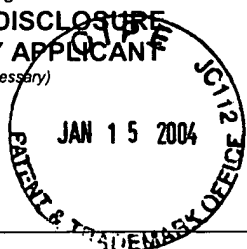
\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

Application Number	09/689136
Filing Date	October 12, 2000
First Named Inventor	Engelhardt, John
Group Art Unit	1636
Examiner Name	Sullivan, Daniel

Sheet 2 of 2

Attorney Docket No: 875.032US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ENGELHARDT, John, et al., "Compounds And Methods To Enhance Adeno-Associated Virus Transduction", <u>U.S. Provisional Application SN 60/201,089 filed May 2, 2000 (875.032PRV).</u>	
		ENGELHARDT, John, Et Al., "Enhancement Of Muscle Gene Delivery With Pseudotyped Aav-5 Correlates With Myoblast Differentiation", <u>U.S. Provisional Application SN 60/305,204 filed July 13, 2001 (875.053PRV).</u>	
		ENGLEHARDT, John, et al., "Adeno-Associated Virus Vectors", <u>Patent Application Serial Number 10/054665, 875.007us2 (January 22, 2002), 141 pages</u>	
		ENGLEHARDT, John, et al., "Adeno-Associated Virus Vectors and Uses Thereof", <u>Patent Application Serial Number 09/684554, filed October 6, 2000, (875.024us1); 141 pages</u>	
		ENGLEHARDT, John, "Compounds And Methods For Pharmico-Gene Therapy Of Epithelial Sodium Channel Associated Disorders", <u>U.S. Provisional Application SN 60/512,347 filed October 16, 2003 (875.085PRV).</u>	
		ENGLEHARDT, John, et al., "Compounds And Methods To Enhance Raav Transduction", <u>U.S. Provisional Application SN 60/459,323 filed March 31, 2003 (875.074PRV).</u>	
		ENGLEHARDT, John, et al., "Pseudotyped Adeno-Associated Viruses And Uses Thereof", <u>U.S. Patent Application SN 10/194,421 filed July 12, 2002 (875.053US1).</u>	
		QING, K., et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro and Murine Tissues In Vivo", <u>Journal of Virology, 72 (2), (Feb. 1998), pp. 1593-1599</u>	
		RENDAHL, Katherine G., et al., "Regulation of gene expression in vivo following transduction by two separate rAAV vectors", <u>Nature Biotechnology (1998) Vol. 16, 757-761</u>	
		WESTFALL, T. D., et al., "The ecto-ATPase inhibitor ARL 67156 enhances parasympathetic neurotransmission in the guinea-pig urinary bladder", <u>European Journal of Pharmacology, 329, (1997), pp. 169-173</u>	
		YAN, ZIYING, et al., "Trans-splicing vectors expand the utility of adeno-associated virus for gene therapy", <u>PNAS, 97 (12), (June 6, 2000), pp. 6716-6721</u>	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

**S/N 09/689136**

**PATENT** JAN 15 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: John F. Engelhardt et al.

Examiner: Daniel M. Sullivan

Serial No.: 09/689136

Group Art Unit: 1636

Filed: October 12, 2000

Docket: 875.032US1

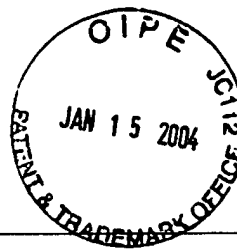
Title: COMPOUNDS AND METHODS TO ENHANCE RAAV TRANSDUCTION

**COMMUNICATION CONCERNING RELATED APPLICATIONS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Applicants would like to bring to the Examiner's attention the following related applications in the above-identified patent application:

<u>Serial/Patent No.</u>	<u>Filing Date</u>	<u>Attorney Docket</u>	<u>Title</u>
60/086166	May 20, 1998	875.005PRV	ADENO-ASSOCIATED VIRUS VECTORS
09/276625 6436392	March 25, 1999	875.007US1	ADENO-ASSOCIATED VIRUS VECTORS
10/054665	January 22, 2002	875.007US2	ADENO-ASSOCIATED VIRUS VECTORS
60/138188	June 8, 1999	875.012PRV	COMPOUNDS AND METHODS TO ENHANCE ADENO-ASSOCIATED VIRUS TRANSDUCTION
09/684554	October 6, 2000	875.024US1	ADENO-ASSOCIATED VIRUS VECTORS AND USES THEREOF
60/201089	May 2, 2000	875.032PRV	COMPOUNDS AND METHODS TO ENHANCE ADENO-ASSOCIATED VIRUS TRANSDUCTION
60/305204	July 13, 2001	875.053PRV	ENHANCEMENT OF MUSCLE GENE DELIVERY WITH PSEUDOTYPED AAV-5 CORRELATES WITH MYOBLST DIFFERENTIATION



10/194421 ✓	July 12, 2002	875.053US1	PSEUDOTYPED ADENO- ASSOCIATED VIRUSES AND USES THEREOF
60/459323 ✓	March 31, 2003	875.074PRV	COMPOUNDS AND METHODS TO ENHANCE rAAV TRANSDUCTION
60/512347 ✓	October 16, 2003	875.085PRV	COMPOUNDS AND METHODS FOR PHARMICO-GENE THERAPY OF EPITHELIAL SODIUM CHANNEL ASSOCIATED DISORDERS

Respectfully submitted,

JOHN F. ENGELHARDT ET AL.

By Applicants' Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6959

Date

January 12, 2004

By

Janet E. Embretson  
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of January, 2004.

**Candis B. Buending**

Name

Signature

Candis B. Buending